

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA, <i>ex rel.</i>)	
DILBAGH SINGH, M.D., <i>et al.</i> ,)	
)	
Plaintiffs,)	CIVIL ACTION NO. 04-186-E
)	
v.)	JUDGE COHILL
)	
)	
BRADFORD REGIONAL MEDICAL CENTER,)	
<i>et al.</i> ,)	
)	
Defendants.)	
)	

RELATORS' CONCISE STATEMENT OF MATERIAL FACTS

Pursuant to Local Rule 56.1(B)(1), Relators hereby submit the following Concise Statement of Material Facts in support of their Motion for Summary Judgment.

1.

Drs. Peter Vaccaro and Kamran Saleh are the owners of V&S Medical Associates, LLC (“V&S”), a medical practice located in Bradford, Pennsylvania. Saleh Dep., p. 6, 9-10 (Apx., Doc. 3).¹ Drs. Vaccaro and Saleh both practice internal medicine. *Id.*, p. 9-10; Vaccaro Dep., p. 7-8 (Apx., Docs. 3, 4).

2.

Prior to 2001, Drs. Vaccaro and Saleh were a significant source of referrals to BRMC, both for inpatient admissions and for outpatient procedures, including diagnostic tests performed

¹ “Apx.” refers to the Appendix in Support of Relators’ Motion for Summary Judgment, filed contemporaneously herewith.

on a nuclear imaging camera located at BRMC. Vaccaro Dep., p. 18-20, 24; Saleh Dep., p. 17-22; BRMC 30(b)(6) Dep., p. 97, 129, 175; Leonhardt Dep., p. 18 (Apx., Docs. 3, 4, 2, 1).

3.

In March 2001, upon learning of V&S's plans to acquire their own nuclear camera, BRMC's CEO, George Leonhardt, asked BRMC's senior vice president of operations, Glen Washington, for information about Vaccaro and Saleh's nuclear medicine referrals, in order to determine "what kind of impact could that have on us." Leonhardt Dep., p. 94-95; BRMC 30(b)(6) Dep., p. 67 (Apx., Docs. 1, 2).

4.

Washington informed Leonhardt that annual gross nuclear medicine revenues were approximately \$2,798,578, of which approximately \$2,274,094 were outpatient revenues. Leonhardt Dep., Exhibit 10 (at HOSP0004401) (Apx., Doc. 13). Washington told Leonhardt that Drs. Vaccaro, Saleh, and Jamil (another physician who rented space in V&S's office) ordered 42.5% of the hospital's nuclear studies, and that V&S had enough nuclear medicine patients to support their own machine. *Id.* (at HOSP0004402); *see also* Saleh Dep., p. 7-8 (Apx., Doc. 3).

5.

Because Drs. Vaccaro and Saleh were a major referral source to the hospital, Leonhardt became concerned that their acquisition of a nuclear camera would have a "very detrimental impact" on the hospital, including on its ability to hire a full-time cardiologist and start a cardiology practice. BRMC 30(b)(6) Dep., p. 94, 97, 116-17; Leonhardt Dep., p. 5-6 (Apx., Doc. 2, 1).

6.

Leonhardt believed that if physicians such as V&S performed nuclear imaging procedures in-house rather than referring them to the hospital, a cardiologist might believe that the hospital would not have enough business to support his practice. Leonhardt Dep., p. 6, 10, 14; BRMC 30(b)(6) Dep., p. 97, 105 (Apx., Docs. 1, 2).

7.

On April 3, 2001, Mr. Leonhardt met with Drs. Saleh and Vaccaro and explained that their acquisition of a nuclear camera would negatively impact the hospital's financial position and affect the recruitment of a cardiologist. Saleh Dep., p. 38-40, 61 and Exhibit 4 (Apx., Docs. 3, 18).

8.

Between April 3 and June 1, 2001, Mr. Leonhardt met with Drs. Vaccaro and Saleh on several more occasions. Saleh Dep., p. 62 and Exhibit 4 (Apx., Docs. 3, 18). In a subsequent letter, Mr. Leonhardt noted that the parties discussed the possibility of entering into a joint venture "within the Safe Harbor exceptions to Stark II." Saleh Dep., p. 62 and Exhibit 4 (Apx., Docs. 3, 18). However, despite these discussions, Vaccaro and Saleh decided to go ahead with their plans. Saleh Dep., p. 38-40 (Apx., Doc. 3).

9.

In May 2001, BRMC adopted a Policy on Physicians with Competing Financial Interests. The policy provided that, if a physician had a financial relationship with a competing health care entity that may have a significant impact upon the hospital, that physician would be ineligible for hospital privileges. BRMC 30(b)(6) Dep., p. 83, 86-87 (Apx., Doc. 2).

10.

In June 2001, V&S entered into a 63-month lease with General Electric (“GE”) for a nuclear camera. Saleh Dep., p. 164-65 and Ex. 33 (Apx., Docs. 3, 38). Drs. Vaccaro and Saleh each executed personal guaranties in favor of GE. (Apx., Doc. 50, at V&S00375-00378, V&S00383, V&S02267-02270, V&S00681-00684).

11.

After the GE camera was placed in V&S’s office, their referral practices changed with respect to nuclear imaging. Rather than referring patients to BRMC for nuclear imaging tests as they had done previously, Drs. Vaccaro and Saleh began to perform such tests in their own office, thus decreasing their nuclear referrals to BRMC. Saleh Dep., p. 37 and Ex. 8; Vaccaro Dep., p. 25; BRMC 30(b)(6) Dep., p. 128 ; Leonhardt Dep., p. 6-7 (Apx., Docs. 3, 21, 4, 2, 1). However, their referral practices with respect to inpatient admissions and other outpatient procedures did not change as a result of acquiring the nuclear camera. Saleh Dep., p. 37 (Apx., Doc. 3).

12.

BRMC was concerned that V&S might reduce its other inpatient and outpatient referrals to the hospital. Among other things, although V&S did not currently offer CT scans or MRIs in their office, BRMC was concerned that they might begin to do so, thus reducing their referrals to the hospital for such procedures. Leonhardt Dep., p. 57-58 and Exhibit 4 (at HOSP0007444); BRMC Dep., p. 160-62 and Exhibit 14 (at HOSP0007444) (Apx., Docs. 2, 7).

13.

After adopting the policy against competing interests, Mr. Leonhard told Drs. Vaccaro and Saleh that they were subject to the policy and faced the possibility of losing their hospital privileges if they continued competing against the hospital. Leonhardt Dep., p. 19; Saleh Dep., p.

43-45; Vaccaro Dep., p. 42 (Apx., Docs. 1, 3, 4).

14.

On January 22, 2002, attorney Marc Raspanti sent a letter to George Leonhardt, stating that the hospital's actions "violate federal law, in particular, the federal anti-kickback criminal statute." This letter also noted that the Stark statute and the False Claims Act provide civil penalties "for those who enter into arrangements which compensate based upon referrals." The letter asserted that "The Medical Center is conditioning privileges on referrals streams. This is precisely the type of arrangement that the anti-kickback laws were intended to prevent." Saleh Dep., Ex. 5, at V&S00124-00125 (Apx., Doc. 19).

15.

On February 15, 2002, Mr. Raspanti sent another letter to Mr. Leonhardt, noting that "the anti-kickback laws are violated even where only 'one purpose' of a payment or exchange is to induce referrals." Mr. Raspanti also noted that, since July 2001, Drs. Vaccaro and Saleh had been subject to numerous case reviews, and that "[s]uch harassment of physicians who are perceived as having a financial conflict of interest is an absolute abuse of the peer review process." Mr. Raspanti stated that "We know of no case that more clearly establishes a hospital's attempt to extract an exclusive referral stream from a physician." Saleh Dep., Ex. 7; Leonhardt Dep., p. 21-22, 76-77 and Ex. 6 (Apx., Doc. 20, 1).

16.

On June 11, 2002, Mr. Leonhardt sent a letter to Drs. Vaccaro and Saleh notifying them that the board had preliminarily determined they were in violation of the policy against competing interests. The letter indicated that the parties should meet to discuss "[w]hether there is interest ... in working together in regard to the equipment and services in question, be it through a joint

venture or other appropriate mean.” Saleh Dep., Ex. 9 (Apx., Doc. 22).

17.

In a June 26, 2002 letter, Leonhardt proposed that the parties enter into a “under arrangements” venture, under which physicians on the hospital medical staff would form a physician-owned diagnostic center to provide diagnostic tests. This diagnostic center would enter into a contract with BRMC, whereby the center would be paid a fixed amount for each test furnished to hospital patients. The hospital, not the diagnostic center, would then bill the patient or third-part payors for the service. Saleh Dep., Ex. 4, 11; BRMC 30(b)(6) Dep., Ex. 11 (Apx., Docs. 18, 23). This proposed “under arrangements” venture would not simply provide nuclear imaging tests, but would also provide other diagnostic procedures such as CTs and MRIs, which were not then being provided by V&S. Leonhardt Dep., p. 72-73; BRMC 30(b)(6) Dep., p. 161; Saleh Dep., p. 35-36 (Apx., Docs. 1, 2, 3).

18.

In his letters to Vaccaro and Saleh, Leonhardt stressed the need to structure the venture in such a way that it satisfied the Stark statute. Saleh Dep., Ex. 4, 11; BRMC 30(b)(6) Dep., Ex. 11 (Apx., Docs. 18, 23).

19.

In a January 17, 2003 letter to BRMC’s counsel, V&S’s attorney, Marc Raspanti, stated that:

In [a January 10, 2003] letter, the Medical Center directly threatens to revoke the medical staff privileges of Drs. Saleh and Vaccaro based upon their refusal to be coerced into a poor medical, and even worse business, decision.... The Medical Center’s conduct is shocking, disappointing and, quite frankly, economic blackmail.

Saleh Dep., Ex. 15, at V&S 00560, 00561 (Apx., Doc. 26). Mr. Raspanti asked for “[a]ll

opinions concerning the legality of the nuclear camera venture” contemplated by BRMC, stating that “I am sure that we can all agree that neither party wishes to become involved in a business venture which is in violation of federal or state law.” *Id.* at V&S00562.

20.

In a February 5, 2003 letter, another of V&S’s attorneys, Edward Kabala, stated that:

While the “under arrangements” process may be entirely legal, we would want to be sure that we will get an unconditional opinion or an advisory opinion from the Office of the Inspector General, to the effect that the final arrangement and the process that led to it would not be deemed inappropriate.

Saleh Dep., Ex. 16, at V&S 01642; Kabala Dep., Ex. 3 (Apx., Doc. 27).

21.

The parties considered it essential that an OIG advisory opinion about the legality of the venture be obtained before entering into any under arrangements venture. BRMC 30(b)(6) Dep., p. 138; Saleh Dep., p. 101. (Apx., Doc. 2, 3).

22.

At some point in early 2003, the parties began discussing an alternative resolution, under which BRMC would agree to sublease the nuclear camera from V&S. BRMC 30(b)(6) Dep., p. 126-27, 139, 151 and Ex. 15; Saleh Dep., p. 116-18 and Ex. 21 (Apx., Docs. 2, 28, 3, 29).

23.

In a February 11, 2003 letter, V&S’s attorney stated that “[m]y clients have indicated that all of their Nuclear Medicine Studies can be accommodated by a combination of their current camera and those at BRMC.” Leonhardt Dep., p. 37 and Exhibit 2 (at V&S 01629) (Apx., Docs. 1, 40).

24.

On April 16, 2003, the parties entered into an Agreement providing that the parties would enter into a sublease for the nuclear camera, while continuing efforts to develop an under arrangements venture. Drs. Vaccaro and Saleh individually signed this Agreement, agreeing to be bound by its terms. Saleh Dep., p. 160-62 and Ex. 31; Vaccaro Dep., p. 49 (Apx., Docs.3, 37, 4).

25.

Before entering into a final sublease, BRMC had a “fair market value” assessment prepared by an accountant, Charles Day. The purported purpose of this report was to determine whether BRMC was paying fair market value under the proposed sublease arrangement. George Leonhardt considered and relied on this report before executing the Equipment Sublease. BRMC 30(b)(6) Dep., p. 147-48; Leonhardt Dep., p. 54-56 (Apx., Docs. 2, 1).

26.

In performing his fair market value analysis, Mr. Day compared the revenues BRMC expected to generate with the sublease in place to the revenues it expected to receive without the sublease in place. The projections were based on the expectation that V&S would refer such business to the hospital if the sublease arrangement were approved. Leonhardt Dep., p. 55-56 and Exhibit 4, p. 17 (Apx., Docs. 1, 7).

27.

George Leonhardt had to obtain board approval to enter into the sublease arrangement. He prepared a summary of the sublease arrangement to use in his presentation to the board. This summary indicated that BRMC expected to generate \$402,000 in profit from the additional nuclear imaging referrals expected to be made by V&S following execution of the sublease. Leonhardt made a presentation to the board and obtained formal approval for the sublease arrangement. Leonhardt Dep., p. 65-72 and Exhibit 5 (Apx., Doc. 1, 8).

28.

On or about October 1, 2003, the parties entered into an Equipment Sublease, pursuant to which BRMC agreed to sublease the GE camera from V&S for a five-year period. During the first term of the sublease agreement, BRMC agreed to make monthly payments to V&S in the amount of \$30,200. Of this amount, \$6,545 was for the actual sublease of the nuclear camera, and reflected a “pass-through” payment of amounts due under V&S’s primary lease with GE. The remaining \$23,655 constituted payment for a purported “non-compete” agreement by V&S and Drs. Vaccaro and Saleh. BRMC Dep., p. 142-143, 183-185 and Exhibit 20 (at HOSP0007684) (Apx., Docs. 2, 12).

29.

Drs. Saleh and Vaccaro individually signed the Equipment Sublease, agreeing to be bound by the terms and conditions of Section 14. Saleh Dep., p. 163 and Exhibit 32; Vaccaro Dep., p. 49 (Apx., Docs.3, 12, 4).

30.

The parties did not seek or obtain an advisory opinion on the legality of the arrangement from the Office of the Inspector General before entering into the Equipment Sublease. BRMC 30(b)(6) Dep., p. 191.

31.

The purpose of the sublease was not simply to acquire a piece of equipment. BRMC 30(b)(6) Dep., p. 140, 146, 154-157; Leonhardt Dep., p. 57 (Apx., Doc. 2).

32.

Mr. Leonhardt hoped and expected to get substantial referrals from Vaccaro and Saleh as a result of the sublease. BRMC 30(b)(6) Dep., p. 146, 154-157; Leonhardt Dep., p. 57 (Apx., Docs. 2, 1).

33.

At the time it entered into the sublease, BRMC had one nuclear camera of its own, and wanted to obtain a second camera. George Leonhardt acknowledged, however, that BRMC did not need three cameras. Leonhardt Dep., p. 49-50 (Apx., Doc. 1).

34.

BRMC did not believe that the GE camera was suited to its long-term needs, and knew that it would shortly replace the GE camera with another camera. BRMC Dep., p. 74-78; Leonhardt Dep., p. 49, 78 (Apx., Doc. 2, 1). (Apx., Doc. 2).

35.

When the Equipment Sublease was entered into, there were only about three years left in the term of V&S's primary lease with GE. BRMC 30(b)(6) Dep., p. 144 (Apx., Doc. 2).

36.

The Equipment Sublease stated that “[s]ubsequent to the execution of this Sublease, the Equipment will be moved to the Sublessee [i.e., BRMC].” Equipment Sublease, p. 4 (Apx., Doc. 12). George Leonhardt believed that other physicians would not want to have their diagnostic work done at V&S's office. Leonhardt Dep., p. 40 (Apx., Doc. 1).

37.

Although the sublease stated that the GE camera would be delivered to BRMC's hospital, BRMC did not, in fact, ever take possession of the camera. Rather, BRMC left the camera in

V&S's offices. BRMC paid V&S \$2,500 per month in rent, as well as payments for secretarial and other administrative expenses (on top of the sublease payments), to keep the camera at V&S's office. BRMC Dep., p. 74-75; Saleh Dep., p. 152-58 and Exhibit 30 (Apx., Docs. 2, 3, 41).

38.

Following the execution of the Equipment Sublease, BRMC paid V&S a billing fee equal to 10% of all collections for tests performed on the GE camera. Saleh Dep., p. 152-154 and Exhibit 30 (Apx., Docs. 3, 41).

39.

V&S billed BRMC the following amounts for billing services, based upon its collections:

<u>Statement Date</u>	<u>Amount</u>
November 2003	\$2,492.23
December 2003	\$2,764.27
January 2004	\$4,243.84
March 2004	\$2,926.83
April 2004	\$817.33
June 2004	\$3,075.57

Saleh Dep., p. 151-160 and Exhibit 30 (Apx., Docs. 3, 41).

40.

In connection with its use of the GE camera following the execution of the Equipment Sublease, V&S made actual payments to BRMC (after deductions for space rental, 10% billing fee, and other charges) of the following amounts: \$4,593.94 (November 2003); \$4,317.68 (December 2003); \$7,652.33 (February 2004); \$6,715.37 (March 2004). For the October 2003 invoice, BRMC made a net payment to V&S of \$4,879.84. The final invoice in June 2004 showed an amount due from BRMC of \$1,090.29. Saleh Dep., p. 151-160 and Exhibit 30 (Apx., Docs. 3, 41).

41.

The GE camera was used for four or five months, through about March 2004, after which it was not used to perform nuclear tests. Saleh Dep., p. 158; Leonhardt Dep., p. 78 (Apx., Doc. 3, 1).

42.

BRMC, V&S, and Philips Medical Capital, LLC (“Philips”) entered into a transaction for a new Philips nuclear camera. V&S entered into a five-year lease with Philips for a nuclear camera, with a monthly rental fee of \$4,450.40 (adjusted periodically). In addition, Philips paid approximately \$200,000 to GE as an early termination fee to buy out the GE lease. V&S agreed to repay this amount in 60 monthly installments of \$3,958.13 (adjusted periodically). BRMC executed a guaranty of V&S’s obligations to Philips. Leonhardt Dep., p. 82-85 and Exhibit 7 (Apx., Doc. 1, 10).

43.

Since the execution of the Philips lease documents, BRMC has reimbursed V&S for its payments under the Philips lease, and has also reimbursed V&S for its payments to Philips relating to the buyout of the GE camera. In addition, BRMC pays V&S \$2,299.14 per month for a Philips service agreement. Such payments continue to the present. Leonhardt Dep., p. 81-89 (Apx., Doc. 1; Apx., Doc. 50, at HOSP0003717-3719). The payments for the Philips camera and Philips service agreement are scheduled to run through January 2010; the payments for the buyout of the GE camera are scheduled to run through December 2009; and the “noncompete” payments under the Equipment Sublease are scheduled to run through September 2008. (Apx., Doc. 50, at HOSP0003717-3719).

44.

Although the lease agreement was between Philips and V&S, the Philips camera was not placed in V&S's office, but was placed in the hospital. BRMC and V&S did not enter into a written sublease agreement with respect to the Philips camera. Leonhardt Dep., p. 89; Saleh Dep., p. 52-53, 164 (Apx., Docs. 1, 3).

45.

Upon the early buyout of the GE lease, V&S obtained ownership of the GE camera. In December 2006, V&S made a charitable donation of the GE camera to Hamot Medical Center. (Apx., Doc. 50, at V&S03319-20).

46.

Since at least January 1, 2006, Dr. Saleh has had a contract with BRMC to serve as a Case Management Medical Director. Under these agreements, Dr. Saleh is paid \$2,000 per month by BRMC. Dr. Saleh testified that he had a similar contract for a period of time before January 1, 2006, although he could not remember how long before. In addition, since at least March 1, 2006, Dr. Saleh has had a separate contract with BRMC to provide certain internal medicine services for Bradford Recovery Systems, for which he is paid a specified amount. Dr. Saleh testified that he might have had a similar agreement prior to March 1, 2006. Saleh Dep., p. 170-176 (Apx., Doc. 3).

47.

Since at least March 1, 2006, Dr. Vaccaro has had a contract with BRMC to provide certain internal medicine services for Bradford Recovery Systems, for which he is paid \$2,000 per month. Dr. Vaccaro testified that he might have had a similar contract for a prior year. Vaccaro Dep., p. 50-52 (Apx., Doc. 4).

48.

George Leonhardt would not have entered into the sublease arrangement if knew that BRMC would receive no referrals from Vaccaro and Saleh. Leonhardt Dep., p. 53 (Apx., Doc. 1).

49.

BRMC has submitted numerous claims to Medicare for inpatient and outpatient hospital services, and has received payment for such claims, where Drs. Vaccaro or Saleh were identified as the attending physician in box 82 of the UB-92 claim form. Responses to Relators' Second Request for Admissions to Bradford Regional Medical Center, Request No. 1 (Apx., Docs. 45, 46, 47).

50.

Such claims were submitted electronically using the UB-92 format. BRMC 30(b)(6) Dep., p. 12-17, 26 (Apx., Doc. 2).

51.

For inpatient claims, the "attending" physician is the same as the admitting physician. For outpatient claims, the "attending" physician is the same as the ordering physician. BRMC's 30(b)(6) Dep., p. 18, 20 (Apx., Doc. 2).

This 10th day of September, 2008.

Respectfully submitted,

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Certificate of Service

I hereby certify that on September 10, 2008, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will automatically send email notification of such filing to the following attorneys of record:

Daniel M. Mulholland, III
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This 10th day of September, 2008.

Respectfully submitted,

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